

## EXHIBIT 114



## Opioid Abuse – What More Can Walgreens Do?

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February 9, 2016

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## Opioid Use – The Problem

Opioids – a group of drugs that include heroin and prescription pain medications

- Euphoric effects caused by drug binding to mu opioid receptor in brain

In 2012, **259 million** opioid prescriptions were written

Opioid prescription sales have increased by **300%** since 1999

In 2013, **2 million** Americans 12 or older reported they abused or were dependent on opioid pain medications

In 2013, **16,000** Americans died from opioid pain medication related overdoses – this is four times greater than related deaths in 1999



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Improving the way opioids are prescribed for safer chronic pain treatment. CDC website. Available at CDC.gov. Accessed January 27, 2016.

2

## Drug Overdose Deaths

Overdose deaths from opioids (including pain medications, illicit fentanyl and heroin) were involved in 28,647 deaths in 2014, which is an increase of 14% from the previous year

### Rate of overdose deaths:

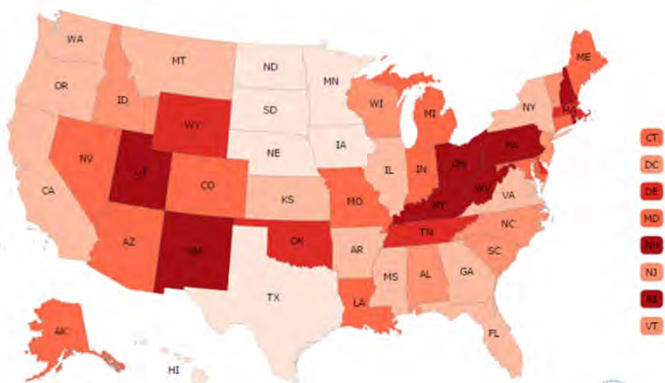
**Synthetic opioids other than methadone** (eg. Fentanyl, tramadol) = 1.8/100,000 people

**Heroin:** 3.4/100,000 people

**Natural/ semisynthetic opioids** (eg. Morphine, oxycodone, hydrocodone) = 3.8/100,000

2014 Age- adjusted death rate per 100,000 people

- 11.1 to 13.5
- 13.6 to 16.0
- 16.1 to 18.5
- 18.6 to 21.0
- 21.0 to 35.5



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Drug overdose deaths by state, US 2013 and 2014. CDC website. Available at [cdc.gov/drugoverdose/data/statedeaths.html](http://cdc.gov/drugoverdose/data/statedeaths.html). Accessed January 27, 2016.



3

## Opioid Abuse Background

Abuse of opioids is caused by addiction – a progressive disease that can be prevented and treated

Average annual healthcare costs for those that abuse opioids are about 8 times higher than those that do not abuse

Those who receive higher doses of opioids are at greater risk for overdose

History of mental health disorders increase risk for prescription opioid misuse

- History of illicit drug and cannabis use, and alcohol abuse are risk factors for opioid abuse

No screening tools can confirm opioid misuse/abuse - no factors identify chronic pain patients that will abuse/misuse prescription opioids



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Sehgal N, et. al. (2012) Pain Physician, 15: E567-E592. Owen J.A. (2014) Journal of the American Pharmacists Association, 54: e5-e15. Fact Sheet, opioid abuse in the United States. Office of National Drug Control Policy (2014).

4

## Opioid Deaths

Increases in death rates from overdose related to increased availability of opioid prescriptions:

- Increased prescribing of opioid pain medications – misuse can lead to opioid abuse in some patients
- Lack of capacity to treat opioid abuse
- Increased availability of illicit fentanyl
- Increased use of heroin (may be driven by those seeking lower priced alternative and it is easier to obtain than Rx opioids)
- Prescribing of large quantities of opioid pain medications to those who don't have a medical reason ("pill-mills")
- Purchase of opioid from dealer or stranger (those at highest risk of overdose are 4 times more likely than average user to get from a dealer)



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Drug overdose deaths hit record numbers in 2014. CDC website. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6109a1.htm> Accessed January 27, 2016. Wilson M. relationship between nonmedical prescription opioid use and heroin use. NEJM 2016. Prescribing data. CDC website. Available at: <http://www.cdc.gov/drugoverdose/prescribing/> Accessed December 18, 2016.

5

## Pharmacists in the Middle

Pharmacists must find a balance :

- Ensure patients in pain are getting legitimate/appropriate prescriptions
- Those seeking medications for diversion or abuse are not dispensed the medications

Identification of a red flag is not a clear indicator that patient is abusing/misusing opioid pain medications

- Red flags suggests that further investigation is needed
- Important for pharmacists to document information they find during conversations with prescriber and patient



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Sehgal N. et. al. (2012) Pain Physician. 15: ES67-ES92. Owen J.A. (2014) Journal of the American Pharmacists Association. 54: e5-e15.

6

## Treat all Patients the Same: "Universal Precautions"

All chronic pain patients should be evaluated to ensure safe and effective use of opioid prescription medications

- Opioid assessment screening tools have some use (but are not fully validated in all populations)
- Urine drug testing – has evidence to favor use
- Use of state prescription monitoring programs – pharmacists and prescribers can access these
- Opioid treatment agreements – evidence that effect in reducing opioid misuse is weak
- Abuse deterrent formulations – have promise, but need further validation they prevent abuse



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7



## What is Being Done to Address the Problem

In 2011 White House released strategy for responding to the prescription drug problem in America

- Federal agencies work with states to educate and implement prescription drug monitoring programs
- Facilitate proper medication disposal – Rx take back initiatives
- Support enforcement of pill mills
- Support development of abuse-resistant formulations for opioid pain medications

In 2015 Secretary of Health and Human Services announced Secretary's Opioid Initiative, which aims to reduce addiction and mortality by:

- Reforming opioid prescribing practices
- Expanding access to overdose reversal drug naloxone
- Expand access to treatment for opioid use disorder



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Understanding the epidemic. CDC website, available at <http://www.cdc.gov/drugoverdose/factsheets/>. Accessed January 27, 2016. Fact Sheet: opioid abuse in the United States. Office of National Drug Control Policy (2014). Opioid Abuse in the U.S. and HHS actions to address opioid-drug related overdoses and deaths. March 26, 2015. Department of Health and Human Services website. [Aspe.hhs.gov](http://www.hhs.gov)

8

## What is Being Done to Address the Problem cont.

States have or are developing prescription monitoring programs

- Most states have electronic databases that collect data about prescribing and dispensing controlled substances

CDC working with experts to develop opioid prescribing guidelines for chronic pain (excludes end of life care) – focus on:

- When to initiate/continue opioids
- Opioid selection, dosage, etc.
- Assessing risk and addressing harms of opioid use

PQA endorsed 3 new measures to address opioid abuse/misuse in non-cancer patients

- Opioid High Dosage
- Multiple prescribers and multiple pharmacies
- Multi-provider, High dose



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Improving the way opioids are prescribed for safer chronic pain treatment. CDC website. Available at CDC.gov. Accessed January 27, 2016. Owen J.A. (2014) Journal of the American Pharmacists Association. 54: e5-e15.

9

States with PDMPs have lower increases in opioid misuse/abuse than other states – thus there is evidence to support these programs may impact opioid abuse.

Measure 1 (opioid high dosage): proportion of individuals without cancer receiving prescriptions for opioids with a daily dosage greater than 120 mg morphine equivalent dose for 90 consecutive days or longer

Measure 2 (multiple prescribers and multiple pharmacies): proportion of individuals without cancer receiving prescriptions for opioids from four or more prescribers AND four or more pharmacies

Measure 3 (multiple prescribers and multiple pharmacies) proportion of individuals without cancer receiving prescriptions for opioids with a daily dosage greater than 120 mg morphine equivalent dose for 90 days or longer AND who received opioid prescriptions from four or more prescribers AND four or more pharmacies.

PQA currently developing new opioid overdose measure – currently undergoing review (Heidi Hilker participated in MDT to develop this measure) – this measure focuses on rate of opioid overdose hospitalizations and ED visits. It is currently meant to be a health plan focused measure.

## What is Walgreens Doing to Address the Problem

Internal team develops, maintains and trains stores on policies and procedures for dispensing controlled substances

- Good Faith Dispensing policy focuses on any controlled substance prescription
- Target Good Faith Dispensing policy focuses on oxycodone, hydromorphone, and methadone prescriptions

Use prescription data to identify high risk prescribers - Dr. Karen Babos follows-up with those individuals

Enlist assistance from SOC to understand store execution on policies

Regular communication with field to address their questions, offer support, training, and guidance for opioid dispensing



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10

## What Additional Strategies can Walgreens Implement

- Survey stores to gain feedback regarding areas of confusion and where additional needs are
- Provide additional pharmacist education to support their role in proper dispensing of controlled substances
- Work w/ external organizations to offer patient education (including opioid naive patients)
- Gain additional resources to offer greater field support for policy execution
- Review checklists to determine if staff is taking appropriate action based on red flags identified (this may be used to enhance training or work with specific individuals)
- Work with Rx Renewal team to ensure the needs of dispensing of controlled substances can be met with less manual work on the stores to fulfill policy requirements
- Identify teams within Walgreens that can provide support for this team (i.e. Clinical Office, Rx Renewal, Government Affairs, etc.)
- Work with government affairs to push enhancements with state prescription drug monitoring programs
- Determine if additional analytics may be used to support staff (i.e. use of "heat" mapping)



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11

## Appendix

## Key Elements of Good Faith Dispensing Policy

For any patient RPH does not have established relationship with, a government ID must be obtained - Documentation of patient/person dropping off Rx must be made on hard copy or scanned into system

Confirm prescriber's DEA number and state license number

May use prescription drug monitoring program (PDMP) to help determine validity of RX (not all states have on-line access)

Contact prescriber for verification or clarification (not always needed) – document pertinent info, such as: prescriber information, diagnosis, length of therapy, medical history, allergies, etc. – document Rx not valid per prescriber if applicable



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13

## Key Elements of Target Good Faith Dispensing Policy

Must use TD-GFD checklist for all single ingredient oxycodone, hydromorphone or methadone – meant to assist staff in identifying red flags warranting action

Review IC plus comments to ensure no location refused to dispense prescription

If concerns noted: RPH should talk with patient/prescriber and document information

All these prescriptions need to have the following attached:

- PDMP report
- Checklist
- Printed ID of person dropping off Rx and image of person picking up (if unknown)

If RPH determines Rx not to be dispensed – must document in patient comments section, keep copy of refused prescription and all documentation



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14